



A DOCPHOENIX

APPL PARTS

IMIS _____
Internal Misc. Paper
LET _____
Misc. Incoming Letter

371P _____
PCT Papers in a 371 Application

A... _____
Amendment Including Elections

ABST _____
Abstract

ADS _____
Application Data Sheet

AF/D _____
Affidavit or Exhibit Received

APPENDIX _____
Appendix

ARTIFACT _____
Artifact

BIB _____
Bib Data Sheet

CLM _____
Claim

COMPUTER _____
Computer Program Listing

CRFL _____
All CRF Papers for Backfile

DIST _____
Terminal Disclaimer Filed

DRW _____
Drawings

FOR _____
Foreign Reference

FRPR _____
Foreign Priority Papers

IDS _____
IDS Including 1449

NPL _____
Non-Patent Literature

OATH _____
Oath or Declaration

PET. _____
Petition

RETMAIL _____
Mail Returned by USPS

SEQLIST _____
Sequence Listing

SPEC _____
Specification

SPEC NO _____
Specification Not in English

TRNA _____
Transmittal New Application

CTNF _____
Count Non-Final

CTRS _____
Count Restriction

EXIN _____
Examiner Interview

M903 _____
DO/EO Acceptance

M905 _____
DO/EO Missing Requirement

NFDR _____
Formal Drawing Required

NOA _____
Notice of Allowance

PETDEC _____
Petition Decision

OUTGOING

CTMS _____
Misc. Office Action

1449 _____
Signed 1449

892 _____
892

ABN _____
Abandonment

APDEC _____
Board of Appeals Decision

APEA _____
Examiner Answer

CTAV _____
Count Advisory Action

CTEQ _____
Count Ex parte Quayle

CTFR _____
Count Final Rejection

INCOMING

AP.B _____
Appeal Brief

C.AD _____
Change of Address

N/AP _____
Notice of Appeal

PA. _____
Change in Power of Attorney

REM _____
Applicant Remarks in Amendment

XT/ _____
Extension of Time filed separate

Internal

SRNT _____
Examiner Search Notes

CLMPTO _____
PTO Prepared Complete Claim Set

ECBOX _____
Evidence Copy Box Identification

WCLM _____
Claim Worksheet

WFEE _____
Fee Worksheet

File Wrapper

FWCLM _____
File Wrapper Claim

IIFW _____
File Wrapper Issue Information

SRFW _____
File Wrapper Search Info

BACKFILE DOCUMENT INDEX SHEET

Office Action Summary

Application No.

09/696,872

Applicant(s)

ROTHMAN, JAMES E.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-26, 28-35, 37 and 44-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 20-26, 28-35, 37, and 44-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's response, on February 24, 2003, Paper No. 11, to the first Office Action on the Merits of this case is acknowledged. It is acknowledged that applicants have cancelled Claims 27 and 36, amended Claims 20-26, 28-35, and 37, and added Claims 44-75. Claims 20-26, 28-35, 37 and 44-75 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 20-26, 28, 44, 46, 48, 50-56, 72, and 74 drawn to methods for increasing the secretion of a protein by a cell, classified in class 435, subclass 7.2.
- II. Claims 29, in part, 30-35, 37, 45, 47, 49, 57, 59-71, 73, and 75, drawn to a method for promoting the release of a heat shock protein/antigenic peptide complex from a cell, classified in class 424, subclass 278.1.
- III. Claims 29, in part, and 58, drawn to a method for promoting the release of a heat shock protein/antigenic peptide complex from a cell including introducing a nucleic acid encoding the heat shock protein, classified in class 424, subclass 278.1.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and

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materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The methods of Inventions I and II are independent as they produce different results. The methods of Inventions I and III are independent as, they produce different results. The methods of Invention II and Inventions III are independent because they comprise different steps and utilize different products.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Claims 23-26, 28, 44 and 46 as well as 32-35, 37, and 45 include the following species of oligomerization domain:

Pentamerization domain,

Trimerization domain,

Derived from a cartilage matrix protein,

Derived from phospholamban,

Derived from thrombospondin,

TSP3,

TSP4,

SEQ ID NO: 1,

SEQ ID NO: 2,

SEQ ID NO: 7,

SEQ ID NO: 3,

SEQ ID NO: 4,

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SEQ ID NO: 5, and

SEQ ID NO: 6.

These species of Claims 23-26, 28, and 44, and 46 as well as 32-35, 37, and 45 are patentably distinct because they are physically and functionally distinct chemical entities.

Claims 48 and 49 as well as 75 and 75 include the following species of KDELr inhibitor protein:

SEQ ID NO: 13 or the protein encoded by SEQ ID NO: 14,
SEQ ID NO: 15 or the protein encoded by SEQ ID NO: 16,
SEQ ID NO: 17 or the protein encoded by SEQ ID NO: 18,
SEQ ID NO: 19 or the protein encoded by SEQ ID NO: 20,
SEQ ID NO: 21 or the protein encoded by SEQ ID NO: 22,
SEQ ID NO: 23 or the protein encoded by SEQ ID NO: 24,
SEQ ID NO: 25 or the protein encoded by SEQ ID NO: 26,
SEQ ID NO: 27 or the protein encoded by SEQ ID NO: 28,
SEQ ID NO: 29 or the protein encoded by SEQ ID NO: 30, and
SEQ ID NO: 34 or the protein encoded by SEQ ID NO: 35.

These species of Claims 48 and 49 as well as 75 and 75 are patentably distinct because they are physically and functionally distinct chemical entities.

Claims 50-53, 56 as well as 57 and 59 includes the following species of methods for expressing the protein in a cell:

Naturally occurring,

Expressed as a result of introduction of a nucleic acid,

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Introducing a nucleic acid molecule encoding the protein, and

Introducing the protein into the cell using microvesicles.

These species of Claims 50-53, 56 as well as 57 and 59 are patentably distinct because they are methods that utilize different products, use different steps, and/or produce different results.

Claims 54 and 55 as well as 60 and 61 include the following species of moiety conjugated to the KDELr inhibitor:

Sugar,

Folate,

Insulin,

Transferrin,

PEG, and

Antigenic peptide.

These species of Claims 54 and 55 as well as 60 and 61 are patentably distinct because they are physically and functionally distinct chemical entities.

Claims 62-71 include the following species of cancer, infective agent, or oncogene-associated protein to be released with the KDELr inhibitor:

Sarcoma,

Lymphoma,

Leukemia,

Melanoma,

Breast cancer,

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Prostate cancer

Ovarian cancer,

Cervical cancer,

Uterine cancer,

Colon cancer,

Lung cancer,

Glioblastoma,

Astrocytoma,

Virus,

Protozoan,

Mycoplasma,

Fungus,

Yeast,

Parasite,

Prion,

Papilloma,

Herpes,

Retrovirus,

Hepatitis,

Influenza,

Rhinovirus,

Respiratory syncytia virus,

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Cytomegalovirus

Adenovirus,

HIV1,

HIV2,

Salmonella,

Staphylococcus,

Streptococcus,

Enterococcus,

Clostridium,

Escherichia,

Klebsiella,

Vibrio,

Mycobacterium,

Tumor suppressor gene,

Defective p53,

Oncogene,

Ras,

Src,

Erb,

Fos,

Abl, and

myc.

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These species of Claims 62-71 are patentably distinct because they are physically and functionally distinct chemical entities.

Claims 72 as well as 73 include the following species of sequences at the carboxy-terminus of the KDELr inhibitor: X-Asp-Glu-Leu where X is:

Lys,

His, and

Asp.

These species of Claims 72 and 73 are patentably distinct because they are physically and functionally distinct chemical entities.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of oligomerization domain, KDELr inhibitor protein, method for expressing the protein, conjugated moiety, cancer, infective agent, or oncogene-associated protein to be released, and carboxy-terminus of the KDELr inhibitor, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Thus, applicant is required to elect one of Inventions I, II, and III and one species within each category described above. Currently, Claims 20, 21, 23, 24, 25, 26, 29, 30, 32, 33, 35, 54, 55, 58, 60-75 are generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.


REBECCA E. PROUTY
PRIMARY EXAMINER
~~09/01/2009~~
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